

REMARKS

A clean copy of amended claims 1-3 is submitted herewith.

The Examiner rejected claims 1-12 under 35 U.S.C. § 112, first paragraph, asserting that Applicant's written description fails to teach the use of fluid silicone gel as presently claimed. Furthermore, the Examiner asserts that the claim term "fluid silicone gel" renders the claims indefinite under 35 U.S.C. § 112, second paragraph, and requests that the Applicant disclose the degree of viscosity of the silicone gel.

Applicant has amended claims 1-3 in order to better describe the properties of the topical silicone of the present invention and to overcome the cited rejections. Specifically, Applicant has added the words "low viscosity" to modify the topical silicone, and Applicant has removed the word "gel." Such an amendment is supported by the present Specification and by the provisional application (U.S. Application Serial No. 60/063,754, hereinafter the provisional) to which the present application claims priority.

Kelo-Cote, the trade-name of a representative topical silicone used to practice the present invention, is described as a "certified replacement for silicone gel sheeting for the management of hypertrophic scars, keloid scars, and erythema secondary to laser resurfacing or allergic causes." (Provisional, lines 7-9.) Furthermore, when a small amount of Kelo-Cote is applied, "the molecules orient themselves one layer thick once the excess is wiped away from the affected area." (Page 4, lines 2-3 of the present application, and provisional, lines 26-27.)

In contrast to silicone gel sheeting, Kelo-Cote is a low-viscosity fluid silicone that can be dispensed from a squeeze tube onto a desired area of treatment (see Exhibit A, printed from the website www.kelocote.com). The excess low-viscosity fluid silicone is subsequently wiped away to leave a very thin layer of low-viscosity fluid silicone molecules. In light of the amendments to claims 1-3, Applicant believes that the Examiner's rejections based on 35 U.S.C. § 112 are overcome. Withdrawal of the 35 U.S.C. § 112 rejections is respectfully requested.

The Examiner rejected claim 1 under 35 U.S.C. § 102. The Examiner relied upon Lee U.S. Patent No. 5,552,162 (hereinafter Lee) to support this rejection. The Examiner relied upon Lee to teach a method of covering a scar surface with a silicone-based gel. The Examiner specifically referred to Lee, col. 5, lines 5-15.

Lee discloses silicone gel sheeting, not the claimed low viscosity fluid silicone that is capable of being dispensed from a squeeze tube, as required by amended claim 1. Lee, col. 5, lines 5-15 refers to a product known by the trademark Silastic®. Applicant has attached information regarding Silastic obtained from the website www.bhj.org/journal/1998_4000_oct/sp_568.htm as Exhibit B. As the description and figures of

Exhibit B make clear, Silastic® is a silicone gel sheeting product which is not capable of being dispensed from a squeeze tube.

Because claim 1, as amended, requires a low viscosity topical fluid silicone which is capable of being dispensed from a squeeze tube, claim 1 is not anticipated by Lee. Accordingly, Applicant respectfully requests the withdrawal of the rejection of claim 1 based on Lee.

The Examiner rejected claims 1-3 under 35 U. S. C. § 102. The Examiner relied on Pocknell U. S. Patent 4,991,574 (hereinafter Pocknell) to support this rejection. The Examiner cited Pocknell, column 1, lines 56-59 to support this rejection. Pocknell, column 1, lines 56-59 reads: "According to the present invention there is provided a surgical dressing comprising a sheet of silicone gel having a wound facing surface and a distal surface and a film of silicone elastomer laminated to said distal surface."

Again, Pocknell does not discuss the application to a scar of a low viscosity topical fluid silicone which is capable of being dispensed from a squeeze tube, such as the Kelo-Cote low viscosity topical fluid silicone specifically identified in this application and in its grandparent provisional application. As was the case with Lee, Pocknell is specifically recognized in the background of the present application, for example, in the following quote from page 3, lines 12-16 of the present application:

"A variety of treatments for hypertrophic scars and keloids have been advocated in the past. These include intralesional steroids, cryosurgery, radiotherapy, pressure therapy, *silicone gel sheeting*, laser therapy, and excisional surgery. Recurrences remain common, and patient satisfaction is variable. Many patients are also dissatisfied with the increased erythema in the wound."

The specification, page 3, lines 12-16, emphasis added.

Silicone gel sheeting is not amended claim 1's low viscosity topical fluid silicone which is capable of being dispensed from a squeeze tube. Pocknell's laminated silicone elastomer film is even less likely to suggest a low viscosity topical fluid silicone which is capable of being dispensed from a squeeze tube than is Lee's gel sheeting. This is so because Pocknell teaches that *Pocknell's silicone gel sheeting is laminated to a silicone elastomer film to render the silicone gel sheeting less frangible*. Thus, Pocknell neither discloses nor suggests application of a low viscosity topical fluid silicone which is capable of being dispensed from a squeeze tube to a scar. Accordingly, the § 102 rejection of claims 1-3 based on Pocknell is overcome.

The Examiner rejected claims 4-12 under 35 U. S. C. § 103. The Examiner relied upon the combination of Lee and Tankovich, U. S. Patent 5,897,549 (hereinafter Tankovich) to support this rejection. The Examiner relied upon Lee as noted in connection with the 35 U. S. C.


§ 102 rejection of claim 1. The Examiner relied upon Tankovich to teach a method wherein a laser beam is directed to treat a hypertrophic scar. The Examiner calls Applicant's attention specifically to Tankovich, col. 2, lines 39-46.

Claims 4-12 depend directly or indirectly from claim 1 which has now been amended to distinguish more clearly over Lee. Neither Lee nor Tankovich, nor any combination of these two, discloses nor suggests amended claim 1's applying a low viscosity topical fluid silicone which is capable of being dispensed from a squeeze tube to the scar. Therefore, the 35 U. S. C. § 103 rejection based upon the combination of Lee and Tankovich is overcome.

For all of the above reasons, Applicant asserts that the Examiner's rejections have been overcome, and the application is now in condition for allowance. Such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees which may be due to render this response a timely response to the December 4, 2002 official action, to Applicant's undersigned counsel's deposit account 10-0435 with reference to file 6631-27092. A duplicate copy of this authorization is enclosed for this purpose.

Respectfully submitted



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